After Final Office Action of March 20, 2008

AMENDMENTS TO THE CLAIMS

- 1. (Currently Amended) A process for purifying alpha-1-antitrypsin (A1AT) from other protein components in an alpha-1-antitrypsin containing solutions solution from other protein components, comprising:
 - subjecting an alpha-1-antitrypsin containing solution to ion-exchange chromatography;
 - (b) <u>then</u> adding detergents and optionally a solvent for inactivating lipid-enveloped viruses;
 - (c) wherein step (b) is followed by increasing the salt concentration to salt out the detergents.
- 2. (Previously Presented) The process according to claim 1, wherein said alpha-1-antitrypsin containing solution has been obtained from the group consisting of blood plasma or its fractions, a reconstituted plasma fraction IV1 (Cohn), from a recombinantly or transgenically expressed alpha-1-antitrypsin preparation and a fermentation supernantant.
- 3. (Previously Presented) The process according to claim 1, wherein ion-exchange chromatography is performed on an anion-exchange gel.
- 4. (Currently Amended) The process according to claim 1, wherein said virus inactivation according to step (b) is effected with Triton X-100, Polysorbate 80 (Tween 80), tri-n-butyl phosphate or caprylic acid or caprylate, at final concentrations of ≥ 0.1% (w/w) Triton Triton

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 $\underline{X-100}$ and Tween $80, \geq 0.03\%$ (w/w) tri-n-butyl phosphate, ≥ 0.1 mM caprylic acid or

caprylate, with an incubation time of ≥ 0.1 hours.

5. (Previously Presented) The process according to claim 1, wherein the salt concentration of

the solution is brought to ≥ 0.5 M in step (c) and particles formed thereby are removed by

filtration.

6. (Previously Presented) The process according to claim 1, wherein a further chromatography

on hydrophobic chromatographic materials is performed.

7. (Previously Presented) The process according to claim 1, wherein a treatment of the alpha-

1-antitrypsin containing solution with a material comprising heparin in an immobilized form

is performed.

8. (Currently Amended) The process according to claim 5, wherein a further virus inactivation

step is performed afterwards after the filtration of particles formed thereby, the virus

inactivation step comprising pasteurization in the presence of ≥ 0.5 M sodium citrate, amino

acids, sugars or mixtures thereof.

9. (Previously Presented) The process according to claim 1, wherein the ion strength of the

solution is reduced by ultrafiltration, diafilatration, or ultrafiltration and diafiltration.

10. (Previously Presented) The process according to claim 1, wherein a separation of virus

particles is performed with filters having pore sizes of 15-20 nm.

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11. (Previously Presented) The process according to claim 1, wherein the alpha-1-antitrypsin

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solution obtained is stored as a liquid, frozen or freeze-dried preparation.

12. (Currently Amended) Alpha-1-antitrypsin having a purity of > 90%, an activity of ≥ 0.8

PEU/mg in its active form plasma-like form, an IgA content of ≤ 1 mg/ml, a residual

detergent content of < 50 ppm, and a monomer content of > 90%, based on the total amount

of alpha-1-antitrypsin, wherein the active form plasma-like form of alpha-1-antitrypsin has a

maximum activity of 100%.

13. (Currently Amended) The alpha-1-antitrypsin according to claim 12, obtainable by a

process comprising the following steps:

(a) providing an alpha-1-antitrypsin solution;

(b) anion-exchange chromatography;

(c) optionally chromatography on a solid phase which comprises heparin in an

immobilized form;

(d) <u>and/or optionally hydrophobic interaction chromatography (HIC);</u>

(e) virus inactivation with $\geq 0.1\%$ (w/w) Triton Triton X-100 and $\geq 0.03\%$ (w/w) tri-n-

butyl phosphate with an incubation time of ≥ 1 hour at ≥ 15 °C;

(f) addition of salt to increase the ion strength of said solution; and

(g) removal by filtration of particles formed thereby.

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14. (Currently Amended) The alpha-1-antitrypsin according to claim 13, wherein a further virus

inactivation step is performed afterwards after the filtration of particles formed thereby, the

further virus inactivation step comprising pasteurization in the presence of ≥ 0.5 M sodium

citrate, amino acids, sugars or mixtures thereof.

15. (Previously Presented) The alpha-1-antitrypsin according to claim 13, wherein the ion

strength of the solution is reduced by ultrafiltration, diafiltration, or both ultrafiltration and

diafiltration.

16. (Previously Presented) The alpha-1-antitrypsin according to claim 13, comprising a virus

inactivation or a prion depletion step comprising a separation of particles by nanofiltration.

17. (Previously Presented) The alpha-1-antitrypsin according to claim 13, wherein the alpha-1-

antitrypsin solution obtained is stored as a liquid, frozen or freeze-dried preparation.

18. (Previously Presented) A medicament containing alpha-1-antitrypsin according to claim 12

as a sole active ingredient or in combination with anti-inflammatory agents.

19. (Previously Presented) A method of treating a degenerative phenomena of the lung, the

method comprising administering the alpha-1-antitrypsin of claim 12 to a subject in need

thereof.

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(Previously Presented) The alpha-1-antitrypsin of claim 12, wherein the residual detergent

content is < 10 ppm.

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